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Efficacy and Tolerability of Topical Dapsone vs Benzoyl Peroxide in Mild to Moderate Acne Vulgaris Treatment: A Retrospective Study

Hafif-Orta Şiddetli Akne Vulgaris Tedavisinde Topikal Dapson ve Benzoil Peroksitin Etkinlik ve Tolere Edilebilirliği: Retrospektif Bir Çalışma

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ABSTRACT

Aim: Acne vulgaris is a disease of the pilosebaceous unit and a chronic inflammatory process. This study aimed to compare topical 5% dapsone and 10% benzoyl peroxide in terms of efficacy, side effects, and patient satisfaction in mild to moderate acne.
Material and Methods: The patients who applied to the dermatology outpatient clinic with the complaint of acne between June 20, 2022, and September 20, 2022, and were diagnosed with mild and moderate acne vulgaris, were retrospectively evaluated. Forty-eight patients in the dapsone group and 53 in the benzoyl peroxide group were included in this study.
Results: At the end of the treatment, a statistically significant difference was found between the two groups in terms of ISGA values and improvement percentage in ISGA, improvement was higher in the dapsone group (both p=0.001). A statistically significant difference was found between the groups in terms of the percentage decrease in lesion counts of closed comedones, papules and pustules, inflammatory and total lesions (decreasement was higher in the dapsone group, p=0.038 for closed comedones, p=0.006 for total lesions and p<0.001 for others). There was no dissatisfied patient in the group using dapsone (p<0.001). Among the side effects, erythema was more common during the whole treatment, and dryness and burning-stinging sensation were higher at the end of the first month in the benzoyl peroxide group.
Conclusion: Topical 5% dapsone is effective in the treatment of mild to moderate acne and is safe in terms of side effects compared to topical 10% benzoyl peroxide.
Keywords: Acne vulgaris; benzoyl peroxide; dapsone.

ÖZ

Amaç: Akne vulgaris, pilosebase ünitenin bir hastalığıdır ve kronik inflamatuar bir süreçtir. Bu çalışmanın amacı hafif ve orta şiddetli akne hastalarında, topikal %5'lik dapson ile topikal %10'luk benzoil peroksiti etkinlik, yan etki ve hasta memnuniyeti açısından karşılaştırmaktır.
Gereç ve Yöntemler: Dermatoloji polikliniğine 20 Haziran 2022 ile 20 Eylül 2022 tarihleri arasında akne şikayeti ile başvuran ve hafif ve orta şiddette akne vulgaris tanısı almış olan hastalar geriye dönük olarak değerlendirildi. Bu çalışmaya, dapson grubunda 48 ve benzoil peroksit grubunda 53 hasta dahil edildi.
Bulgular: Tedavi sonunda, ISGA değerleri ve ISGA'daki iyileşme yüzdesi açısından iki grup arasında istatistiksel olarak anlamlı bir farklılık bulundu, dapson grubunda iyileşme daha fazlaydı (her ikisi için de p=0,001). Kapalı komedon, papül ve püstül, inflamatuvar lezyon ve toplam lezyonların lezyon sayılarındaki azalma yüzdeleri açısından iki grup arasında istatistiksel olarak anlamlı bir farklılık bulundu (dapson grubunda azalma daha fazlaydı, kapalı komedonlar için p=0,038, toplam lezyonlar için p=0,006 ve diğerleri için p<0,001). Dapson kullanan grupta memnun olmayan hasta yoktu (p<0,001). Yan etkiler arasında eritem tüm tedavi süresi boyunca daha sık görüldü, kuruluk ve yanma-batma hissi benzoil peroksit grubunda birinci ayın sonunda daha fazlaydı.
Sonuç: Topikal %5'lik dapson, hafif ve orta şiddetli akne tedavisinde etkilidir ve topikal %10 benzoil peroksit ile karşılaştırıldığında yan etki açısından güvenlidir.
Anahtar kelimeler: Akne vulgaris; benzoil peroksit; dapson.

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INTRODUCTION

Acne vulgaris (AV) is a chronic inflammatory process affecting the pilosebaceous unit. It is usually seen during adolescence. It has significant psychological and social impacts on patients. The treatment options for acne include topical products, systemic antibiotics, and systemic isotretinoin (1,2). Topical retinoids, benzoyl peroxide (BPO), and topical or systemic antibiotics combined with retinoids or BPO are the first-line options in treating mild to moderate acne. For nodulocystic acne, short-term systemic steroids or intralesional steroid injections may be used. BPO, one of the frequently used topicals in acne treatment, has a lipophilic nature, easily penetrates the pilosebaceous unit, and has bactericidal, anti-inflammatory, and comedolytic effects. Topical dapsone, which has both antibacterial and anti-inflammatory properties, has recently been used in the topical management of other inflammatory diseases, including acne. This retrospective study aimed to compare the efficacy, side effects, and patient satisfaction of topical 5% dapsone and 10% BPO in patients with mild and moderate AV.

MATERIAL AND METHODS

The study protocol was approved by the clinical research ethics committee of Hitit University (date: 09.11.2022, and no: 2022-96). The study was conducted in accordance with the Declaration of Helsinki and an informed consent form was obtained from all participants.

The study was conducted retrospectively by reviewing the patient files. We included the files of patients who applied to the dermatology outpatient clinic with the complaint of acne and were diagnosed with mild and moderate AV based on the investigator's static global assessment (ISGA) scores between 2 and 4, who were between 12 and 40 years of age, and who used topical 5% dapsone or topical 10% BPO once a day in the evening between June 20, 2022, and September 20, 2022. We excluded the files of patients who had previously used medicines containing same active ingredients in the study, who had severe acne with nodulocystic lesions, who were under 12 or over 40 years of age, and who had received other acne treatment within the 3 months before admission to the hospital, epilation or other application (energy-based device, peeling, dermabrasion, etc.) on the face in the last month, users of systemic corticosteroids, facial retinol, or acidic cosmetic products, those with a history of PCOS or other hormonal diseases. After all these eliminations, a total of 101 patient files with appropriate criteria, 48 patients in the dapsone group and 53 patients in the BPO group were included in the study. Demographic characteristics, ISGA scores before and after treatment, the number of non-inflammatory lesions including open and closed comedonal lesions, the number of inflammatory lesions including papules and pustules, side effects and severity scores at the end of each month (0 for absent, 1 for mild, 2 for moderate, 3 for severe), and satisfaction scores (1-not satisfied, 2-satisfied, 3-very satisfied) in files were recorded for the study.

The examination of the patients, determination of disease severity, treatments and treatment follow-ups, efficacy and side effects follow-ups, and file reviews were performed by the same doctor (SH). None of the patients in the study discontinued treatment due to side effects.

Statistical Analysis

The IBM SPSS Statistics v.25 (Armonk, NY: IBM Corp.) program was used for data recording and statistical tests. The Kolmogorov-Smirnov test was used to determine whether the continuous variables fit the normal distribution. Among the continuous variables, those that fit the normal distribution were expressed as the mean and standard deviation, and those that did not fit the normal distribution were expressed as the median and min-max. Categorical variables were expressed as numbers and percentages. The chi-square test was used to compare independent groups in terms of categorical variables. In cases where the smallest expected value was less than 5, the Fisher exact test was used instead of the chi-square. The Wilcoxon test was used to investigate the difference between dependent groups in terms of variables that did not fit the normal distribution, and the Mann-Whitney U test was used for independent groups. For the statistical significance level, $p<0.05$ was accepted.

RESULTS

A total of 101 patient files, 48 patients in the dapsone group and 53 patients in the BPO group were included in the study. The mean age of the patients using dapsone was 22.38±7.94 years, while it was 20.53±8.18 years for those using BPO. The percentage of males was 18.8% (n=9) in the dapsone group and 18.9% (n=10) in the BPO group. There was no statistically significant difference between the groups in terms of gender and age (p=0.988, and p=0.103, respectively).

When the groups were investigated in terms of ISGA scores (p=0.469), open (p=0.530) and closed (p=0.208) comedone counts, non-inflammatory lesions (p=0.110), papules (p=0.385) and pustules (p=0.529), inflammatory lesion (p=0.265), and total lesion counts (p=0.105) before treatment, there was no significant difference (Table 1).

Both groups showed a significant difference in terms of pre- and post-treatment ISGA values and the number of lesions ($p<0.001$ for all). This indicates that both drugs were effective in treatment.

Table 1. General demographic and clinical characteristics of the patients

	Dapsone (n=48)	BPO (n=53)	p
Age (years)	22.38±7.94	20.53±8.18	0.103
Gender, n (%)			
Male	9 (18.8)	10 (18.9)	0.988
Female	39 (81.2)	43 (81.1)	
Initial ISGA	2.85±0.77	2.96±0.76	0.469
Initial ISGA, n (%)			
2	18 (37.5)	16 (30.2)	
3	19 (39.6)	23 (43.4)	0.736
4	11 (22.9)	14 (26.4)	
Initial NIL	42.43±9.66	43.49±9.52	0.110
Open comedone	10.96±3.04	11.49±3.49	0.530
Closed comedone	31.19±6.71	32.00±6.42	0.208
Initial IL	37.17±5.82	38.53±6.51	0.265
Papule	13.71±1.54	14.09±1.88	0.385
Pustule	23.46±4.34	23.87±4.14	0.529
Initial TL	80.02±15.27	81.47±15.11	0.105

ISGA: investigator's static global assessment, NIL: non-inflammatory lesion count, IL: inflammatory lesion count, TL: total lesion count, BPO: benzoyl peroxide

There was a statistically significant difference between the groups in ISGA values and improvement percentage in ISGA at the end of the treatment (both p=0.001). The dapsone group had lower ISGA values and a higher improvement percentage in ISGA after 3-month treatment. There was also a significant difference between the groups both in the number of lesions and the decrease percentage in the number of lesions for closed comedones (p=0.021, and p=0.038, respectively), papules (both p<0.001) and pustules (both p<0.001), inflammatory lesions (both p<0.001), total lesions (p=0.004, and p=0.006, respectively). The dapsone group had lower counts of all lesion types and a higher improvement percentage in lesion counts after 3 months of treatment. No difference was found in terms of both lesion counts and percentage reduction for open comedones (p=0.062, and p=0.115, respectively), and non-inflammatory lesions (p=0.340, and p=0.284) between groups (Table 2).

Table 2. ISGA measurements, lesion counts, and percent decrease at the end of the third month

	3rd-month of Treatment			Percent Decrease at the End of Treatment		
	Dapsone (n=48)	**BPO (n=53)**	**p**	**Dapsone (n=48)**	**BPO (n=53)**	**p**
ISGA	0.84 [0-3]	1.38 [0-3]	**0.001**	71 [0-100]	51.83 [0-100]	**0.001**
NIL	8.6 [0-38]	17.84 [0-38]	0.062	80.67 [28.3-100]	58.45 [20.83-100]	0.115
Open comedone	2.72 [0-11]	4.98 [0-10]	0.340	76.02 [16.67-100]	56.87 [14.29-100]	0.284
Closed comedone	5.88 [0-27]	12.86 [0-29]	**0.021**	82.19 [28.95-100]	58.99 [18.18-100]	**0.038**
IL	5.84 [0-28]	11.52 [0-27]	**<0.001**	84.71 [30-100]	69.76 [32.5-100]	**<0.001**
Papule	2.6 [0-11]	4.94 [0-10]	**<0.001**	81.43 [28.57-100]	65.38 [23.08-100]	**<0.001**
Pustule	3.24 [0-18]	6.58 [0-18]	**<0.001**	86.66 [30.77-100]	72.23 [30.77-100]	**<0.001**
TL	14.44 [0-66]	29.36 [0-64]	**0.004**	82.53 [29.55-100]	63.83 [27.27-100]	**0.006**

ISGA: investigator's static global assessment, NIL: non-inflammatory lesion count, IL: inflammatory lesion count, TL: total lesion count, BPO: benzoyl peroxide, descriptive statistics were presented as median [minimum-maximum]

The patient satisfaction levels were found statistically significantly different between the groups (p<0.001). None of the patients in the dapsone group were dissatisfied, and the proportion of very satisfied patients was lower in the BPO group (Table 3).

There was a statistically significant difference between the groups in terms of erythema at the end of each month during the 3 months of treatment (p<0.001, p=0.022, and p=0.016, respectively). Erythema was more common in the BPO group in all monthly follow-ups. When the severity of erythema for each month was compared between the two groups, there was only a statistically significant difference at the end of the 1st month (p=0.029, severe erythema was not seen in the dapsone group, but was more common in the BPO group), but not at the end of the 2nd month (p>0.999). At the end of the 3rd month, no erythema was observed in the dapsone group.

There was also a statistically significant difference between the two groups in terms of dryness at the end of the 1st and 2nd month (p<0.001, and p=0.049, respectively), but not in the 3rd month (p=0.059). Dryness was also more common in patients using BPO. When the severity of dryness was compared between the groups, there was a significant difference at the end of the 1st month (p=0.001, severe dryness was not observed in the dapsone group, but was more common in the BPO group), but not at the end of 2nd, and 3rd months (p=0.101, and 0.182, respectively).

When the difference between the two groups in terms of burning-stinging was investigated, there was a significant difference at the end of the 1st month (p<0.001, more common in the BPO group), but not at the end of 2nd, and 3rd months (p=0.111, and p=0.101, respectively). When the severity of the burning-stinging sensation was compared, there was a significant difference at the end of each three months of treatment (p<0.001 for all), between the two groups (Table 4).

Table 3. Satisfaction levels of the patients

	Dapsone (n=48)	**BPO (n=53)**	**p**
Satisfaction, n (%)			
Very satisfied	22 (45.8)	4 (7.5)	
Satisfied	26 (54.2)	31 (58.5)	**<0.001**
Not satisfied	0 (0.0)	18 (34.0)	

BPO: benzoyl peroxide

DISCUSSION

Dapsone (4-amino4-diphenyl sulfone) is a drug from the sulfone group discovered in 1908 and it is mainly used to treat leprosy, but also in the treatment of dermatitis herpetiformis, vasculitis, and neutrophilic dermatoses. It competitively inhibits dihydropteroate synthetase with para-aminobenzoic acid (inhibits dihydrofolic acid production) and has both anti-inflammatory and antimicrobial activity (3-5). It has an antibacterial effect on Cutibacterium acnes (4). Some studies have shown that dapsone inhibits neutrophil migration by suppressing interleukin (IL)-8 release, which is important in neutrophil chemotaxis, prevents B2 integrin from binding to neutrophils, suppresses myeloperoxidase-induced ionization and cytotoxicity of neutrophils, and inhibits leukotriene B4-mediated chemotactic response of neutrophils by preventing its binding to neutrophils (6-9).

Systemic usage has side effects such as hemolytic anemia, methemoglobinemia, agranulocytosis, peripheral neuropathy, vertigo, headache and hearing loss, nausea-vomiting, abdominal pain, and eosinophilic pneumonia (4,10,11). Checking glucose-6-phosphate dehydrogenase levels, liver function tests and complete blood count before treatment and repeating the tests during the treatment period may reduce side effects. There are also cases of dapsone-associated photodermatitis reported during the treatment of linear Ig-A dermatosis with oral dapsone (12).

Table 4. Side effect data in groups by month

	Dapsone (n=48)			BPO (n=53)		
	1st-month	**2nd-month**	**3rd-month**	**1st-month**	**2nd-month**	**3rd-month**
Erythema, n (%)	3 (6.3)	1 (2.1)	0 (0.0)	27 (50.9)	8 (15.1)	6 (11.3)
Erythema, n (%)						
Mild	2 (4.2)	1 (2.1)	0 (0.0)	5 (9.4)	3 (5.7)	5 (9.4)
Moderate	1 (2.1)	0 (0.0)	0 (0.0)	2 (3.8)	3 (5.7)	1 (1.9)
Severe	0 (0.0)	0 (0.0)	0 (0.0)	20 (37.7)	2 (3.8)	0 (0.0)
Dryness, n (%)	6 (12.5)	4 (8.3)	3 (6.3)	30 (56.6)	12 (22.6)	10 (18.9)
Dryness, n (%)						
Mild	4 (8.3)	4 (8.3)	3 (6.3)	3 (5.7)	5 (9.4)	8 (15.1)
Moderate	2 (4.2)	0 (0.0)	0 (0.0)	5 (9.4)	3 (5.7)	2 (3.8)
Severe	0 (0.0)	0 (0.0)	0 (0.0)	22 (41.5)	4 (7.5)	0 (0.0)
Burning/Stinging, n (%)	10 (20.8)	8 (16.7)	5 (10.4)	35 (66)	16 (30.2)	12 (22.6)
Burning/Stinging, n (%)						
Mild	6 (12.5)	8 (16.7)	5 (10.4)	2 (3.8)	5 (9.4)	10 (18.9)
Moderate	4 (8.3)	0 (0.0)	0 (0.0)	2 (3.8)	6 (11.3)	2 (3.8)
Severe	0 (0.0)	0 (0.0)	0 (0.0)	31 (58.5)	5 (9.4)	0 (0.0)

BPO: benzoyl peroxide

No serious side effects have been reported in topical use, and we did not see any serious side effects in our study.

There was no significant difference between the two groups compared in this study in terms of demographic characteristics, pre-treatment ISGA values, and the number of lesions. When each group was evaluated separately, a statistically significant difference was found in the ISGA values and the lesion counts before and after the 3-month treatment, which shows that both treatment methods are effective for mild and moderate acne independently. When the groups were compared in terms of percentage improvements in the number of lesions, there was a higher improvement in the number of papules, pustules, and inflammatory lesions as well as the number of closed comedones in the dapsone group. Considering the main effect of dapsone, it is understandable that it improves inflammatory lesions, but the mechanism of the 68% improvement in closed comedones is not fully understood and this issue requires further studies. When the two groups were compared in terms of patient satisfaction, it was seen that there were no dissatisfied patients in the dapsone group, and the number of very satisfied patients in the BPO group was lower compared to the dapsone group. Side effects were more common in patients using BPO, especially in the 1st month of the treatment. The possibility of side effects is well-known in the application site of BPO.

The literature review found that most studies compared topical dapsone with placebo, and there were only a few studies in combination with systemic treatments.

Faghihi et al. (13) compared the efficacy and side-effect profile of systemic 20 mg/day isotretinoin + 5% dapsone and systemic 20 mg/day isotretinoin + placebo treatments in a 12-week treatment period in 58 moderate and severe acne patients aged 18-25 years in their placebo-controlled, randomized study. They found a significant improvement in the inflammatory lesion counts at the end of the treatment in the dapsone group compared to the other group, but no difference in the acne score between the placebo group. In our study, we observed a significant improvement in the number of inflammatory lesions in the group using dapsone. However, in our study, there was also a significant difference between the two groups in closed comedones and disease severity (improvement was greater in the dapsone group). They also found that dapsone was more effective in adult females.

Del Rosso et al. (14) conducted a 16-week study of 20 acne patients with trunk involvement and reported that the patients using 7.5% dapsone once a day had a decrease of 74% in the number of inflammatory lesions, 69% in the number of non-inflammatory lesions, and 72% in the total number of lesions. In our study, we also found similar results, we observed an improvement of 84% in inflammatory lesions, 65% in non-inflammatory lesions, and 74% in total lesion counts.

Tanghetti et al. (15) investigated the tolerability and efficacy of 5% dapsone applied twice daily in male and female acne patients and observed higher recovery rates and greater reductions in the number of lesions in female patients after 12 weeks of treatment. When we looked at the recovery percentages at the end of treatment in our study, we observed higher improvements in ISGA scores, closed comedones, papules, pustules, and inflammatory lesions in females.

Draelos et al. (16) evaluated 3010 people in 2 multicenter, 12-week, double-blind, randomized phase 3 studies and showed that 5% dapsone applied twice a day had a significant effect on acne scores compared to the control group (40.5% and 32.8% decrease, respectively). In our study, we found higher improvement rates in the severity score (71% for the dapsone group, and 51% for the BPO group). In the study, they also observed a significant decrease in both non-inflammatory (32% and 24%) and inflammatory (47.5% and 41.8%) acne lesions in the dapsone group compared to the control group (16). In our study, we found higher recovery rates in both the dapsone and BPO-using groups compared to this study. In the follow-ups, they did not see any abnormality (even in those with G-6PD deficiency) in laboratory tests. Side effects such as 21.8% dryness, 20% erythema, 1.4% burning sensation, 1% itching, and 0.1% irritation were observed in the dapsone group. In our study, the rate of erythema and dryness was lower. However, burning and stinging sensations were seen more frequently in our study.

Darjani et al. (17) compared 30 patients using 5% topical dapsone + 100 mg/day systemic doxycycline and 30 patients using 5% BPO + 100 mg/day systemic doxycycline in terms of recovery, side effects, and satisfaction in their randomized study. After 12 weeks of treatment, they found no significant difference between the groups in terms of the number of both inflammatory and non-inflammatory lesions. In the 4th, 8th, and 12th weeks of treatment, skin dryness was more common in the dapsone group than in the other group. Although erythema and irritation were seen more in the group using BPO, this difference was not found to be significant. 78% of the patients in the dapsone group and 69% in the BPO group were satisfied with the treatment result.

Jawade et al. (18) demonstrated that dapsone 5% gel was efficacious and well-tolerated in non-inflammatory and inflammatory acne lesions at the end of 12 weeks.

Kamoji et al. (19) showed that 0.1% adapalene and 1% clindamycin had good efficacy with fewer side effects than dapsone gel 5% for mild to moderate AV.

One of the limitations of the study is its retrospective nature. The treatment periods of the patients included in the study coincided with the summer period (in the cold months, the severity of side effects and patient satisfaction could be different) is among the shortcomings of the study. As there were no severe acne patients among the study patients, the results can not apply to severe acne.

CONCLUSION

Using topical 5% dapsone in the treatment of mild and moderate AV is found effective and safe in terms of side effects compared to topical 10% BPO. Case-control and/or split-face studies with large numbers of patients are needed to clarify this issue.

Ethics Committee Approval: The study was approved by the Clinical Research Ethics Committee of Hitit University (09.11.2022, 2022-96).

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